4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4844]

"Ruby Chocolate" Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the extension of a temporary permit issued to Barry Callebaut U.S.A. LLC (the applicant) to market test products (designated as "ruby chocolate") that deviate from the U.S. standards of identity for cacao products. The extension allows the applicant to continue to evaluate commercial viability of the product and to collect data on consumer acceptance of the product in support of a petition to establish a standard of identity for "ruby chocolate." We also invite other interested parties to participate in the market test.

DATES: The new expiration date of the permit will be either the effective date of a final rule establishing a standard of identity for "ruby chocolate" that may result from the petition or 30 days after denial of the petition.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), we issued a temporary permit to Barry Callebaut U.S.A. LLC, 600 West Chicago Ave, Suite 860, Chicago, IL 60654, to market test products identified as "ruby chocolate" that deviate from the

requirements of the standards of identity for cacao products in part 163 (21 CFR part 163) (84 FR 64541, November 22, 2019). We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for cacao products issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate marketing tests of products identified as "ruby chocolate." These test products deviate from the U.S. standards of identity for cacao products (§§ 163.111, 163.123, 163.124, 163.130, 163.135, 163.140, and 163.145).

For the purpose of this permit, "ruby chocolate" is the solid or semi-plastic food prepared by mixing and grinding cacao fat with one or more of the cacao ingredients (namely, chocolate liquor, breakfast cocoa, cocoa, and low-fat cocoa), citric acid, one or more of optional nutritive carbohydrate sweeteners. "Ruby chocolate" contains not less than 1.5 percent nonfat cacao solids, not less than 2.5 percent by weight of milk fat, not less than 12 percent by weight of total milk solids, not more than 1.5 percent of emulsifying agents, and not more than 5 percent of whey or whey products. It may also contain other ingredients such as antioxidants approved for food use, spices, natural and artificial flavorings, and other seasonings. However, these other ingredients cannot imitate the flavor of chocolate, milk, butter, berry, or another fruit. Additionally, "ruby chocolate" contains no added coloring. The test product "ruby chocolate" contains the principal ingredients used in most of the current standards for cacao products under part 163; however, it deviates from the current standard of identify for chocolate products in terms of its final composition, taste, and color.

On February 19, 2021, the applicant asked us to extend the temporary permit so the applicant could have more time to market test the "ruby chocolate" and gain additional consumer acceptance in support of the petition to establish a standard for "ruby chocolate." We find that it is in the interest of consumers to extend the permit for continued market testing of "ruby chocolate" to gain additional information on consumer expectations and acceptance. Therefore, under § 130.17(i), we are extending the temporary permit granted to Barry Callebaut U.S.A. LLC

for temporary marketing of approximately 60 million pounds (27,215,540 kilograms) of "ruby chocolate" to provide continued market testing of the specified amount of product for the applicant on an annual basis. The test products will bear the name "ruby chocolate." The new expiration date of the permit will be either the effective date of a final rule establishing a standard of identity for "ruby chocolate" that may result from the petition or 30 days after denial of the petition. All other conditions and terms of this permit remain the same.

In addition, we invite interested persons to participate in the market test under the conditions of the permit, except for the designated area of distribution. Any person who wishes to participate in the extended market test should notify, in writing, the Branch Chief, Product Evaluation Labeling Branch, Division of Food Labeling and Standards, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. The notification must describe the amount to be distributed, the area of distribution, and include the labeling that will be used for the test product (see § 130.17(i)). For information on what to include in the notification to FDA, see § 130.17(c). Test products must be labeled in accordance with 21 CFR part 101.

Dated: August 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy

[FR Doc. 2021-19096 Filed: 9/2/2021 8:45 am; Publication Date: 9/3/2021]